K062554

APPENDIX A. 510(k) SUMMARY

FEB 6 2007

A.	**Sponsor/Submitter:**	Abbott Vascular Devices 400 Saginaw Drive Redwood City, CA 94063
B.	**Contact Person:**	Daun Putnam Regulatory Project Manager Phone:(650) 474-3323 Fax:(650) 474-3041
	Date of Submission:	August 25, 2006
	Device Trade Name:	StarClose 6F Dilator
	Device Common Name:	Vessel Dilator
	Device Classification:	Class II
	Regulation Number:	21 CFR 874.1310
	Classification Name:	Vessel, Dilator, for Percutaneous Catheterization
	Product Code:	DRE
	Predicate Device:	Encapsulon Vessel Dilators (K840641) and Super Sheath Introducer Sheath (K052557)
	Intended Use:	The StarClose 6F Dilator is intended for use in procedures requiring percutaneous introduction of intravascular devices.
	Device Description:	The Abbott Vascular StarClose 6F Dilator is a tapered plastic tube with a hub to facilitate handling and an interior channel sized to accept a 0.038 inch guidewire. The dilator goes inside one of the StarClose sheaths to provide support while gaining access to blood vessels prior to catheterization procedures.
	Summary of Substantial Equivalence:	Abbott Vascular has submitted information on indications for use, design and principle of operation, biocompatibility and performance characteristics to establish that StarClose 6F Dilator is substantially equivalent to currently marketed predicate devices. StarClose 6F Dilator has the same intended use as the predicate devices. Results of scientific testing have ensured that all materials are biocompatible, no new adverse effects were introduced and

physical properties are appropriate for the intended use. Non-clinical testing was conducted.

In conclusion, StarClose 6F Dilator has been shown to be substantially equivalent to the Class II predicate devices upon which the dilator is based.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 6 2007

Abbott Vascular Inc.
c/o Veronica Kocken
400 Saginaw Drive
Redwood City, CA 94063

Re: K062554
Trade Name: Vessel Dilator
Regulation Number: 21 CFR 874.1310
Regulation Name: Vessel, Catheter, for Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: December 19, 2006
Received: December 20, 2006

Dear Ms. Kocken:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bachner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX B. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 062554

Device Name: The StarClose 6F Dilator

Indications For Use: The StarClose 6F Dilator is intended for use in procedures requiring percutaneous introduction of intravascular devices.

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109)
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickers

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062554